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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,239	01/19/2006	Hiroshi Kase	00005.001285.	9168
5514 7590 02/02/2009 FITZPATRICK CELLA HARPER & SCINTO 30 ROCKEFELLER PLAZA NEW YORK, NY 10112				
EXAMINER				
MANOHAR, MANU M				
ART UNIT		PAPER NUMBER		
1617				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/565,239

Applicant(s)

KASE ET AL.

Examiner

MANU M. MANOHAR

Art Unit

1617

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-38, 41, 42, 46 and 48 is/are pending in the application.
- 4a) Of the above claim(s) 4-7,10-37,41,42,46 and 48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,8,9 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
- Paper No(s)/Mail Date 9/18/2006

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The status of the Application

This Office Action is in response to applicant's remarks filed on January 06, 2009. Claims 1, 3-38, 41, 42, 46, 48 are pending in the application. Claims 2, 39, 40, 43-45 and 47 are cancelled. Claims 3, 4, 6, 8, 10, 12, 14, 16, 18, 20- 22, 24-29, 31-34, 36-38, 41, 42 and 48 been amended. Claims 1, 3-38, 41, 42, 46, 48 were subjected to restriction and election of species. The details are below.

Election and Restriction

Applicant's election of Group I, claims 1, 3-19, 38 and 42 is acknowledged. The applicants elected the following species: a composition disclosed in Test Example 2 at specification page 33 - a) Compound (I) and b) antidepressant drug (fluoxetine hydrochloride, an elected species). Claims 4-7, 10-19 and 42 from Group I are withdrawn from further consideration as being drawn to nonelected species.

Claims 20-37 and 46 (Group II) and claims 41 and 48 (Group III) are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Groups, there being no allowable generic or linking claim. Applicant's election **without traverse** of the restriction requirement in the reply is acknowledged. The requirement is deemed proper and is therefore made FINAL. **Claim(s) 1, 3, 8, 9, and 38 from Group I are examined herein insofar as they read on the elected invention and species.**

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 38 is rejected under 35 U.S.C. 102(b) as being anticipated by over Shimada et al (WO 99/12546), wherein English version US Patent 6,727,259 is being used.

Shimada et al teaches a xanthine derivative represented by formula (I) (Column 9 claim 1) as claimed in the claim 38, 8-(3,4-dimethoxystyryl)-1,3-diethyl-7-methyl-3,7-dihydro-1H-purine-2,6-dione. Examiner noted that the reference '259 further state formula (I) is used for treating neurodegeneration and it has antagonistic property to adenosine A2-receptor.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham vs John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenlee et al [(WO 03/022283) IDS] in view of Shimada et al (WO 99/12546), wherein English version US Patent 6,727,259 as applied to claim 38 above.

The instant invention is drawn to a pharmaceutical composition comprising adenosine A2A receptor antagonist, a xanthine derivative and an antidepressant drug, a serotonin reuptake inhibitor. The claim 1 is drawn to a composition comprising a compound of formula (I) 8-(3,4-dimethoxystyryl)-1,3-diethyl-7-methyl-3,7-dihydro-1H-purine-2,6-dione of formula (I) (an elected specie) and an antidepressant drug. Claims 3 and 8 are drawn to a serotonin reuptake inhibitor and claim 9 is drawn to a specific a serotonin reuptake inhibitor fluoxetine hydrochloride (an elected specie).

Greenlee et al discloses the composition comprising the combination of adenosine A2A receptor antagonist and an antidepressant drug (Title and abstract) as claimed in the instant claim 1 for treating depression. Greenlee et al also teaches that the antidepressant can be a selective serotonin reuptake inhibitor (page 20, line 21-23).

Further Greenlee et al teaches that the selective serotonin reuptake inhibitor can be fluoxetine (page 20, line 21-23).

Although Greenlee is silent about the salt of fluoxetine, using the salt of the compound, fluoxetine hydrochloride, is obvious to one of the ordinary skill in the art according to the need. The salt formation provides a means of altering the physical properties such as solubility without modifying the chemical structure or biological properties. Moreover fluoxetine, in the form of fluoxetine hydrochloride is a well known antidepressant as 'Prozac' and it would be obvious to use either fluoxetine or fluoxetine hydrochloride in this art based on the requirement in the use.

Greenlee et al do not specifically disclose adenosine A2A receptor antagonist as formula (I).

Shimada et al teaches the compound 8-(3,4-dimethoxystyryl)-1,3-diethyl-7-methyl-3,7-dihydro-1H-purine-2,6-dione represented by the formula (I) (Column 9 claim 1) a xanthine derivative for treating for treating neurodegenerative diseases including anti-depressive disorders and it is a well known adenosine A2A receptor antagonist.

Therefore it would have been *prima facie* obvious to a person of ordinary skill in the art at the time of the instant invention to prepare the composition comprising adenosine A2A receptor antagonist and an antidepressant drug, fluoxetine, as taught by Greenlee et al, by substituting the adenosine A2A receptor antagonist with 8-(3,4-dimethoxystyryl)-1,3-diethyl-7-methyl-3,7-dihydro-1H-purine-2,6-dione as disclosed by Shimada et al.

One of the ordinary skill in the art would be motivated to prepare the composition comprising 8-(3,4-dimethoxystyryl)-1,3-diethyl-7-methyl-3,7-dihydro-1H-purine-2,6-dione and an antidepressant drug, fluoxetine because 1) Greenlee et al teaches the preparation of the combination, comprising adenosine A2A receptor antagonist and an antidepressant drug, fluoxetine. 2) Shimada et al teaches the compound 8-(3,4-dimethoxystyryl)-1,3-diethyl-7-methyl-3,7-dihydro-1H-purine-2,6-dione as formula (I) with adenosine A2A receptor antagonistic activity for anti-depressive action. Both the references teach the composition useful for treating neurological disorders like depression and neurodegenerative diseases. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success to develop a pharmaceutical composition comprising the adenosine A2A receptor antagonist and fluoxetine as taught by Greenlee et al by substituting adenosine A2A receptor antagonist with 8-(3,4-dimethoxystyryl)-1,3-diethyl-7-methyl-3,7-dihydro-1H-purine-2,6-dione as taught by Shimada et al.

Conclusion

Claims 1, 3, 8, 9, and 38 stand rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MANU MANOHAR whose telephone number is (571)270-5752. The examiner can normally be reached on Mon - Thu 9.00AM to 4.00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-270-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MANU MANOHAR
Examiner
Art Unit 1617

MM

/YONG S. CHONG/
Primary Examiner, Art Unit 1617